

REMARKS

After entry of this Amendment, the pending claims are: claims 1-13 and 15-27. The Office Action dated April 26, 2007 has been carefully considered. Claim 14 was previously canceled without prejudice. Claims 1, 6, 7, 9, 13, 16, 19 and 20 have been amended. Independent claims 1 and 20 have been amended without prejudice to clarify what is actually being claimed. The Examiner is thanked for the indication of allowable subject matter in claims 13 and 19. Claims 13 and 19 have been rewritten into independent claim form. Claims 25-27 have been added. No new matter has been added. Reconsideration and allowance of the pending claims in view of the above Amendments and the following Remarks is respectfully requested.

In the Office Action dated April 26, 2007, the Examiner:

- rejected claims 1-13 and 15-19 under 35 U.S.C. §101 as being drawn to non-statutory subject matter;
- rejected claims 1-12, 15-18, and 20-24 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,945,933 to Branch *et al.* (“Branch”) in view of U.S. Patent No. 5,944,658 to Koros *et al.* (“Koros”); and
- objected to claims 13 and 19 as being dependent upon a rejected base claim, but otherwise would be allowable in rewritten in independent claim form to include all of the limitations of the base claim and any intervening claims.

DEPENDENT CLAIMS 13 AND 19

Dependent claims 13 and 19 were objected to as being dependent upon a rejected base

claim, but otherwise would be allowable if rewritten in independent claim form to include all of the limitations of the base claim and any intervening claims. The Examiner is thanked for the indication of allowable subject matter in claims 13 and 19. Claims 13 and 19 have been rewritten into independent claim form. It is respectfully submitted that independent claims 13 and 19 are allowable over the cited prior art. Withdrawal of this objection and allowance of independent claims 13 and 19 is respectfully requested.

35 U.S.C. §101 REJECTION

Claims 1-13 and 15-19 were rejected under 35 U.S.C. §101 as being drawn to non-statutory subject matter. In particular, independent claim 1 was rejected for positively reciting part of a human. As an initial matter, independent claim 1 required a first guide sized and dimensioned to be received within the first guide receiving channel, and to be inserted into an area of bone. It is respectfully submitted that independent claim 1 did not positively recite bone as an element of the claim. Rather, independent claim 1 defines that the end of the guide is sized and dimensioned to be inserted into an area of the bone. Nonetheless, in order to expedite prosecution of the present application, independent claim 1 has been amended to make explicit what was already implicit. Independent claim 1 has been amended to recite a first guide having an end, the end being sized and dimensioned to be insertable into a first area of bone. As amended, independent claim 1 does not positively recite a part of a human. Withdrawal of this rejection and allowance of independent claim 1 is respectfully requested.

INDEPENDENT CLAIM 1

Independent claim 1 has been rejected as being as being unpatentable over Branch in view of Koros. It is respectfully submitted that the Examiner has not identified any reason why a person of ordinary skill in the art would combined Branch with Koros other than it would teach all of the elements of independent claim 1. (*See KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. _____ (2007) “[a] patent composed of several elements is not proved obvious merely by demonstrating that each element was, independently known, in the prior art ... important to identify a reason that would have prompted a person of ordinary skill in the art to combine the elements as the new invention does.”) It is respectfully submitted that the Applicants through their own effort and expense derived the device as claimed in independent claim 1. It is respectfully submitted that without the benefit of the Applicants’ disclosure, it would not be obvious for one of ordinary skill in the art to redesign Branch to incorporate screws for securing the distractor blades to the adjacent vertebrae. If anything, incorporating screws as taught by Koros would be contrary to the explicit teachings of Branch whose purpose was to provide a retractor incorporating a first portion 22 and a second portion 42 wherein the retractor 10 was insertable into a patient’s body so that the first and second portions 22, 42 could be moved with respect to one another, and hence the patient’s tissue could be separated, in order to provide an enlarged working space 50. Incorporating screws as taught by Koros into the first and second portions 22, 42 of Branch would be contrary to the explicit teachings of Branch.

In addition, it is respectfully submitted that even if the combination of Branch and Koros was proper, which in our opinion and judgment it is not, the combination would still not disclose each and

every limitation of independent claim 1. Independent claim 1 requires a frame having a first guide receiving channel; a first tissue retaining wall; a second tissue retaining wall movably coupled to the first tissue retaining wall, wherein one of the first tissue retaining wall and the second tissue retaining wall is coupled to the frame; and a first guide having an end, the first guide being sized and dimensioned to be received within the first guide receiving channel, the end being sized and dimensioned to be insertable into a first area of bone. It is respectfully submitted that neither Branch nor Koros, either alone or in combination, disclose, teach or suggest a first guide having an end, the first guide being sized and dimensioned to be received within the first guide receiving channel, the end being sized and dimensioned to be insertable into a first area of bone.

As admitted by the Examiner, Branch does not disclose, teach or suggest a first guide having an end, the first guide being sized and dimensioned to be received within the first guide receiving channel, the end being sized and dimensioned to be insertable into a first area of bone. Rather, the Examiner relies upon Koros to disclose a first guide having an end, the first guide being sized and dimensioned to be received within the first guide receiving channel, the end being sized and dimensioned to be insertable into a first area of bone. Koros discloses a first retractor frame 10 incorporating a first retractor blade 26 (*i.e.*, a first retaining wall) and a second retractor blade 28 (*i.e.*, a second retaining wall), the first retractor blade 26 being moveable with respect to the second retractor blade 28 so that an enlarged surgical site could be viewed. Koros further discloses a second, offset distractor frame 12, the second distractor frame 12 incorporating a first distractor blade 50 and a second distractor blade 52. The first and second distractor blades 50, 52 each include a slot 58, 60 formed therein, the slots 58, 60 being

sized and configured to receive screws 54, 56. In use, the first retractor frame 10 is inserted into a patient in a fully closed position. Thereafter, the first retractor frame 10 is expanded. Next, the second, offset retractor frame 12 is inserted into the incision with the screw 54, 56 screwed into the patient's vertebrae. The screws 54, 56 hold the second, offset retractor frame 12 firmly in position so that the engaged vertebrae can be distracted.

It is respectfully submitted that at best Koros discloses a retractor blade 50, 52 having a slot formed therein for receiving a screw 54, 56. More particularly, Koros discloses the use of a second retractor system having a pair of retractor blades 50, 52 which are sized and configured to engage adjacent vertebrae so that after an incision is made in a patient, a first retractor system 10 can be inserted to create a surgical site. Thereafter, a second retractor system 12 can be inserted and engaged to the adjacent vertebrae so that the vertebrae can be distracted.

It is respectfully submitted that there is absolutely no disclosure, teaching or suggest of inserting an end of a first guide into a patient's bone while the guide is inserted into a guide receiving channel formed in a retractor. More particularly, it is respectfully submitted that there is absolutely no disclosure, teaching or suggestion in Koros of inserting the end of the screws into the slots 248, 252 formed in the retractor system of Branch. Such a combination would be contrary to the explicit teachings of Branch as it would require the incorporation of additional distractor blades, which include the screws, and which in turn would require Branch to be completely redesigned. It is respectfully submitted that the Examiner is engaging in impermissible hindsight reconstruction wherein elements are being identified in the prior art and are being arranged in the exact manner as currently being claimed

even though arranging the elements in that manner is contrary to the stated intended purpose of the elements .

For at least the above-identified reasons, it is respectfully submitted that neither Branch or Koros disclose, teach or suggest all of the limitations of independent claim 1. Thus, it is respectfully submitted that independent claim 1 is allowable over the cited prior art. Withdrawal of these rejections and allowance of independent claim 1 is respectfully requested.

Furthermore, as claims 2-5, 7-12 and 15-18 all depend from independent claim 1, it is submitted that these claims are equally allowable. Withdrawal of these rejections and allowance of claims 2-5, 7-12 and 15-18 is also respectfully requested.

In addition, as newly added dependent claims 25-27 all dependent from independent claim 1, it is submitted that these claims are equally allowable. Allowance of claims 25-27 is also respectfully requested.

INDEPENDENT CLAIM 6

Dependent claim 6 has been amended into independent claim form. As amended, independent claim 6 requires a retractor comprising a frame having a first guide receiving channel; a first tissue retaining wall; a second tissue retaining wall movably coupled to the first tissue retaining wall, wherein one of the first tissue retaining wall and the second tissue retaining wall is coupled to the frame; a first guide having an end, the first guide being sized and dimensioned to be received within the first guide receiving channel, the end being sized and dimensioned to be insertable into a first area of bone; and a

hinge that joins the first and second retaining walls. It is respectfully submitted that there is absolutely no disclosure in either Branch or Koros of a hinge that joins the first and second retaining walls.

The Examiner relies upon Figure 14 of Branch to disclose a hinge. It is respectfully submitted that Figure 14 discloses a retractor 20 including a first portion 22 having a collar 28 and a second portion 42 having a collar 48, the collars 28, 48 each including a slot 248, 252 formed therein. The slots 248, 252 being sized and configured to receive a pair of cam mechanisms 254, 256. The cam mechanisms 254, 256 each incorporating a lever 258 and a clamping body 260. In use, when it is desired to move the first portion 22 with respect to the second portion 42, the lever 258 is rotated in order to release the clamping body 260. Alternatively, when it is desired to fix the position of the first portion 22 with respect to the second portion 42, the lever 258 is again rotated in order to secure the clamping body 260. In this manner, the cam mechanisms 254, 256 act as locking mechanisms to release and secure the position of the first portion 22 with respect to the second portion 42.

It is respectfully submitted that there is absolutely no disclosure, teaching or suggestion of a hinge that joins the first and second retaining walls. At best, Branch discloses a hinge that connects a lever 258 to a clamping body 260 for securing the position of a first retaining wall with respect to a second retaining wall.

For at least the above-identified reason, it is respectfully submitted that neither Branch or Koros, either alone or in combination, disclose, teach or suggest all of the limitations of independent claim 6.

Thus, it is respectfully submitted that independent claim 6 is allowable over the cited prior art.

Withdrawal of this rejection and allowance of independent claim 6 is respectfully requested.

INDEPENDENT CLAIM 20

Independent claim 20 has been rejected as being as being unpatentable over Branch in view of Koros. In particular, the Examiner asserts that since the apparatus of independent claim 1 would have been unpatentable in view of Branch combined with Koros, the operation of the method steps as set forth in independent claim 20 would have been obviously carried out during operation of that device.

Independent claim 20 requires a method of inserting a tissue retractor into a patient, comprising providing a retractor having paired tissue retracting surfaces and first and second guide receiving areas; percutaneously implanting first and second guides into different areas of bone in the patient; positioning upper ends of the first and second guides through the first and second guide receiving areas, respectively, thereby inserting the retractor into tissue of the patient; and moving the tissue retracting surfaces apart from one another independently of the first and second guides.

For at least the reasons provided above in connection with independent claim 1, it is respectfully submitted that there is absolutely no disclosure, teaching or suggestion in either Branch or Koros, either alone or in combination, of positioning upper ends of the first and second guides through the first and second guide receiving areas. Again, as previously stated, at best Koros discloses inserting a screw through a slot formed in a top portion of a retractor blade. More particularly, Koros discloses inserting a second retractor frame into the working space created by a first retractor frame. The second retractor

frame incorporating a pair of retractor blades that have a pair of screws inserted therein for engaging and distracting adjacent vertebra.

CONCLUSION

A fee of \$550.00 is believed due for this submission (for the addition of two new independent claims and three new dependent claims). The Commissioner is authorized to charge this and any other fee which may now or hereafter be due in this application to Deposit Account No. 19-4709.

In the event that there are any questions, or should additional information be required, please contact Applicants' attorney at the number listed below.

Date: July 26, 2007

Respectfully submitted,

/Giuseppe Molaro/
Giuseppe Molaro
Registration No. 52,039

For: Brian M. Rothery
Registration No. 35,340

Attorney for Applicants
Stroock & Stroock & Lavan LLP
180 Maiden Lane
New York, New York 10038
(212) 806-6114